K043183

Premarket Notification
Epi-K™

Moria

MAR 2 5 2005

510(k) SUMMARY

1. Submitter's identification

a. MORIA S.A.
15, rue Georges Besse
92160 ANTONY
France
Tel: (33-1) 46 74 46 36
Fax: (33-1) 46 74 46 70

b. Contact person: Mélanie RENAUD-SAMIRI
QA & Regulatory Affairs Manager
E mail: mrenaud@moria-int. com
Or
Alain DUPRAT
Chief Executive Officer and President
E mail: aduprat@moria-int. com

c. Date Summary Prepared: November 15, 2004

2. Device name

Trade Name: Epi-K™

3. Classification name

Keratome (per 21CFR section 886.4370)

4. Substantial equivalence

Substantial equivalence is being claimed to the following legally marketed devices:

Trade or Proprietary or Model Name: OneUse - Plus Microkeratome
Manufacturer: MORIA S.A.
510(k) number: K040297

Trade or Proprietary or Model Name: Centurion SES™ Epikeratome
Manufacturer: CIBA Vision Corporation
510(k) number: K032978

Section 4 page 2

Trade or Proprietary or Model Name: EpiTome SYSTEM
Manufacturer: GEBAUER MEDZINTECHNIK GmbH
510(k) number: K041206

5. Submitted device description

List of components

- Power unit and footswitch
- Handpiece / submitted device motor
- Head and blade separator
- Suction rings

a) Power unit and footswitch

The power unit used for the submitted device Epi-K™ is the same as the power unit used for the predicate devices (OneUse - Plus Microkeratome K040297) already legally marketed in the USA by our company.

The power unit includes pumps for producing vacuum.
The power unit has been designed to operate the Keratome by means of electric motor.

The front panel includes several displays and features:
- Vacuum pressure gauge, Battery level indicator,
- Battery charge indicator,
- Connector for the motorized handpiece of the submitted device
- Vacuum outlet connector

The back panel includes connectors for footswitches and battery charger

b) Handpiece / submitted device motor

The submitted device handpiece has two built-in electrical motors (one motor driving the blade separator oscillation and one motor driving the advance of the handpiece across the cornea).

c) Head and blade separator

The submitted device head is disposable and is supplied with a pre-inserted blade separator
The blade separator is made of two parts:
- The metal part in low carbon steel, and
- The plastic holder of the blade separator, which is not in contact with the patient's eye.

d) Suction rings

The suction rings are used to fixate and pressurize the eye and to provide a base for the head. Different rings are available in order to adjust the diameter of the epithelial flap.
The rings are available in two versions:

- Reusable
- Disposable

6. Statement of intended use

The submitted device Epi-K™ is intended for use in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

7. Discussion of tests and results

Epi-keratome predicate devices are already legally marketed and have been used to cleave the epithelium from the cornea (CIBA Centurion SES™ Epikeratome K032978 & GEBAUER EpiTome SYSTEM K041206).

In-vitro studies on porcine eyes with the submitted device Epi-K™ demonstrated:

- The safety and efficacy of the submitted device for creating an epithelial flap
- The quality of the epithelium separation.

In-vivo studies on 77 human eyes showed that the submitted device –Epi-K™ is a safe device able to create a hinged circular epithelial flap of predetermined dimensions.

The intended uses and the operating and separating principles (i.e.; Effectiveness) of the submitted device Epi-K™ are the same as the predicate devices (CIBA Centurion SES™ Epikeratome K032978 & GEBAUER EpiTome SYSTEM K041206).

The operational features of the submitted device Epi-K™ are the same or similar to those offered by the predicate device (MORIA OneUse-Plus Microkeratome K040297).

The safety features of the submitted device Epi-KTM are the same or very similar to those offered by the predicate devices (CIBA Centurion SES™ Epikeratome K032978 & GEBAUER EpiTome SYSTEM K041206).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2005

Moria S.A.
c/o Mélanie Renaud-Samiri
QA & Regulatory Affairs Manager
15 Rue Georges Besse F
92160 Antony
FRANCE

Re: K043183
Trade/Device Name: Epi-K™
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: March 16, 2005
Received: March 18, 2005

Dear Mrs. Renaud-Samiri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 page 1

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name:

Epi-K™

Indications for use:

The Epi-K™ is intended for use in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

Marsha L. Burke Nicholas
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K043183

Prescription Use ✓ AND / OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)